

March 28th, 2024 Revision 4

RESIDUAL SOLVENTS STATEMENT

Urea GMP

BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Urea, Bio Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4. There are no residual solvents added or used in the manufacturing process of Urea, Bio Excipient Grade, and Bio Pharma Grade or its raw materials. BioSpectra analyzes Urea annually for residual solvents with results meeting the specifications of NMT 3000 ppm Methanol, and NMT 5000 ppm Ethanol.

Current Product Number
UREA-3220
UREA-3221
UREA-3222
UREA-3223
UREA-3224
UREA-3250
UREA-4205
UREA-4220

For further information, please contact info@biospectra.us

Cassie Baun

Cassie Baun Senior Compliance Specialist

The information contained herein is the property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure, copying or alteration. Decision based on the use of this information is the sole responsibility and liability of the recipient. If you would like a controlled version of this document, please contact info@biospectra.us